

USSN: 09/616,283; Art Unit: 1645
Attorney Docket No. VRXB-P01-001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

GOODNOW

Serial No: 09/616,283

Filed: July 14, 2000

For: SYSTEM FOR DETECTING
BACTERIA IN BLOOD, BLOOD
PRODUCTS, AND FLUIDS OF
TISSUES

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Art Unit: 1645

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Examiner: J. Hines

Assistant Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration Under 35 U.S.C. §1.132

Sir:

I, Harvey G. Klein, MD., hereby declare as follows:

1. I am the Chief of the Department of Transfusion Medicine at the Warren C. Magnuson Clinical Center, National Institutes of Health. I have been working and conducting research in the field of transfusion medicine for over thirty (30) years. ~~I serve on the Food and Drug Administration's (FDA) Blood Products~~ Advisory Committee. I actively hold leadership positions in the American Association of Blood Banks, the American Blood Commission, the American Society of Hematology, and the American Society of Apheresis. I currently serve as Chairman of the Committee of Revision for Blood and Blood Products for the U.S. Pharmacopeia. I am a diplomat of the American Board of Internal Medicine and a diplomat of the American Board of Pathology. I have authored and co-

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authored more than 175 publications on transfusion medicine. Accordingly, my curriculum vitae is attached as Appendix A.

2. I have read the above-identified application, the pending claims, and the Office Action mailed on September 29, 2003. I have been asked by Verax Biomedical, Inc. to comment upon the meaning of the term "donor" to a person of skill in this area.
3. In the blood banking discipline, the term "donor" is a universally recognized term of art. Federal Law mandates that only healthy and asymptomatic subjects are allowed to donate blood. Prior to donating, each individual must undergo a thorough screening process that includes temperature, pulse, blood pressure, hemoglobin content in the blood, and questions about general health, background and travel. See AABB Association Bulletin #99-10, dated December 2, 1999, attached herewith as Appendix B. See also the blood donation eligibility guidelines as set forth by the American Red Cross, herewith attached as Appendix C. If the donor fails any of these questions/requirements, the individual is turned away from the donation center to prevent provision of adulterated components to blood recipients. Thus, in the blood banking arena the term "donor" means a healthy or asymptomatic subject qualified to donate blood.
4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both,

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under Section 1001 of Title XVIII of the United States Code and that willful false statements may jeopardize the validity of this Application for Patent or any patent issuing thereon.

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Dated: _____

Signature: _____

Dr. Harvey G. Klein
Chief, Department of Transfusion Medicine
Warren C. Magnuson Clinical Center
National Institutes of Health